

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Joseph P. Vacanti, Christopher K. Breuer, Beverly E. Chaignaud
and Toshiraru Shin'Oka

Serial No.: 09/185,360 now
U.S. Patent No. 6,348,069

Art Unit: 3738

Filed: November 3, 1998

Examiner: D. Isabella

Issued: February 19, 2002

For: *ENGINEERING OF STRONG, PLIABLE TISSUES*

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including twenty-seven (27) pages of Form PTO-1449. All of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/185,360, filed November 3, 1998, now U.S. Patent No. 6,348,069, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
1,995,970	03-26-1935	Dorough	260/2
2,609,347	09-02-1952	Wilson	260/2.5
2,653,917	09-29-1953	Hammon	260/2.5
2,659,935	11-24-1953	Hammon	18/55
2,664,366	12-29-1953	Wilson	117/138.8
2,676,945	04-27-1954	Higgins	260/45.7
2,683,136	07-06-1954	Higgins	260/78.3
2,703,316	03-01-1955	Schneider	260/78.3
2,758,987	08-14-1956	Salzberg	260/78.3
2,846,407	08-05-1958	Wilson	260/2.5
2,951,828	09-06-1960	Zeile, et al.	260/77.5
3,514,761	06-02-1970	Sparks	623/66
3,531,561	09-29-1970	Trehu	264/210
3,826,241	07-30-1974	Bucalo	128/1 R
3,880,991	04-29-1975	Yolles	424/22
3,883,393	05-13-1975	Knazek, et al.	195/1.8
3,902,497	09-02-1975	Casey	128/296
3,935,065	01-27-1976	Doerig	195/1.7
3,949,073	04-06-1976	Daniels, et al.	424/177
3,960,150	06-01-1976	Hussain, et al.	128/260
3,974,526	08-17-1976	Dardik, et al.	3/1.4
3,992,725	11-23-1976	Homsy	3/1
3,995,444	12-07-1976	Clark, et al.	62/306
4,026,304	05-31-1977	Levy	128/419
4,060,081	11-29-1977	Yannas, et al.	128/156
4,069,307	01-17-1978	Higuchi, et al.	424/22
4,137,921	02-06-1979	Okuzumi	128/335.5
4,141,087	02-27-1979	Shalaby, et al.	3/1
4,144,126	03-13-1979	Burbidge	195/1.1
4,186,448	02-05-1980	Brekke	3/1.9
4,192,827	03-11-1980	Mueller, et al.	525/123
4,205,399	06-03-1980	Shalaby, et al.	3/1
4,228,243	10-14-1980	Iizuka	435/285
4,239,664	12-16-1980	Teag, et al.	260/17.4
4,243,775	01-06-1981	Rosensaft, et al.	525/415
4,277,582	07-07-1981	Mueller, et al.	525/421
4,280,954	07-28-1981	Yannas, et al.	260/123.7
4,304,591	12-08-1981	Mueller, et al.	71/93
4,304,866	12-08-1981	Green, et al.	435/240
4,328,204	05-04-1982	Wasserman, et al.	424/19
4,347,847	09-07-1982	Usher	128/334

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

4,348,329	09-07-1982	Chapman	260/403
4,352,883	10-05-1982	Lim	435/178
4,356,261	10-26-1982	Kuettner	435/68
4,391,797	07-05-1983	Folkman, et al.	424/19
4,416,986	11-22-1983	Markus, et al.	435/68
4,427,808	01-24-1984	Stol, et al.	524/24
4,431,428	02-14-1984	Schmer	604/897
4,438,198	03-20-1984	Schmer	435/178
4,439,152	03-27-1984	Small	433/173
4,440,921	04-03-1984	Allcock, et al.	528/168
4,444,887	04-24-1984	Hoffmann	435/240
4,446,229	05-01-1984	Indech	435/1
4,446,234	05-01-1984	Russo, et al.	435/29
4,450,150	05-22-1984	Sidman	424/1.1
4,456,687	06-26-1984	Green	435/241
4,458,678	07-10-1984	Yannas, et al.	128/155
4,485,096	11-27-1984	Bell	424/95
4,485,097	11-27-1984	Bell	424/95
4,489,056	12-18-1984	Himmelstein, et al.	424/22
4,494,385	01-22-1985	Kuraoka, et al.	62/306
4,495,174	01-22-1985	Allcock, et al.	424/78
4,505,266	03-19-1985	Yannas, et al.	128/1
4,520,821	06-04-1985	Schmidt, et al.	128/334
4,528,265	07-09-1985	Becker	435/172.1
4,544,516	10-01-1985	Hughes, et al.	264/108
4,545,082	10-08-1985	Hood	623/1
4,553,272	11-19-1985	Mears	623/1
4,559,298	12-17-1985	Fahy	435/1
4,559,304	12-17-1985	Kasai, et al.	435/240
4,563,350	01-07-1986	Nathan, et al.	424/95
4,563,489	01-07-1986	Urist	524/21
4,563,490	01-07-1986	Stol, et al.	524/24
4,576,608	03-18-1986	Homsy	623/11
4,595,713	06-17-1986	St. John	523/105
4,609,551	09-02-1986	Caplan, et al.	424/95
4,627,853	12-09-1986	Campbell, et al.	623/16
4,637,931	01-20-1987	Schmitz	424/73
4,642,120	02-10-1987	Nevo, et al.	623/16
4,645,669	02-24-1987	Reid	424/95
4,675,189	06-23-1987	Kent, et al.	424/490
4,675,284	06-23-1987	Leevy, et al.	435/6
4,681,763	07-21-1987	Nathanson, et al.	424/95
4,689,293	08-25-1987	Goosen, et al.	435/1
4,713,070	12-15-1987	Mano	623/1

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

4,721,096	01-26-1988	Naughton, et al.	128/1
4,734,373	03-29-1988	Bartal	435/296
4,757,017	07-12-1988	Cheung	435/240.23
4,757,128	07-12-1988	Domb, et al.	528/271
4,778,749	10-18-1988	Vasington, et al.	435/2
4,801,299	01-31-1989	Brendel, et al.	623/66
4,891,225	01-02-1990	Langer, et al.	424/428
4,846,835	07-11-1989	Grande	623/11
4,853,324	08-01-1989	Viles, et al.	435/2
4,868,121	09-19-1989	Scharp, et al.	435/268
4,880,622	11-14-1989	Allcock, et al.	424/78
4,886,870	12-12-1989	D'Amore, et al.	528/206
4,888,176	12-19-1989	Langer, et al.	424/426
4,902,289	02-20-1990	Yannas	623/1
4,946,938	08-07-1990	Magill, et al.	528/399
4,963,489	10-16-1990	Naughton, et al.	435/240.1
4,988,761	01-29-1991	Ikada, et al.	524/557
5,032,508	07-16-1991	Naughton, et al.	435/32
5,041,138	08-20-1991	Vacanti, et al.	623/16
5,219,361	06-15-1993	von recum, et al.	623/11
5,324,519	06-28-1994	Dunn, et al.	424/426
5,512,600	04-30-1996	Mikos, et al.	521/61
5,514,378	05-07-1996	Mikos, et al.	424/425
5,772,695	06-30-1998	Orton	623/66
5,855,608	01-05-1999	Brekke, et al.	623/11

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Country</u>
AU-B-24245/88	02-13-1989	Australia
35 18 150	10-23-1986	Germany
28 53 614	07-26-1979	Germany
62 011 459	01-20-1987	Japan
63 074 498	04-04-1988	Japan
63 196 273	08-15-1988	Japan
63 196 595	08-15-1988	Japan
0 153 896	09-04-1985	Europe
0 282 746	09-21-1988	Europe
0 339 607	11-02-1989	Europe
0 226 061	06-24-1987	Europe
0 248 246	06-02-1986	Europe
0 248 247	06-02-1986	Europe
0 361 957	09-29-1989	Europe
0 344 924	05-05-1989	Europe

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

WO 87/06120	10-22-1987	PCT
WO 88/03785	06-02-1988	PCT
WO 89/00413	01-26-1989	PCT
WO 89/07944	09-08-1989	PCT
WO 90/12603	11-01-1990	PCT
WO 90/12604	11-01-1990	PCT
WO 91/01720	02-21-1991	PCT
WO 94/21299	09-24-1994	PCT
WO 92/06702	04-30-1992	PCT
WO 92/07525	05-14-1992	PCT
WO 93/07913	04-29-1993	PCT
WO 93/08850	05-13-1993	PCT
WO 93/16687	09-02-1993	PCT
WO 94/25079	11-10-1994	PCT

Publications

ALLCOCK, H. R., et al., "Synthesis of Poly[(Amino Acid Alkyl Ester)Phosphazenes]¹⁻³," Macromolecules, 10(4) (July/August, 1977).

ALLCOCK, H.R., et al., "Hydrolysis Pathways for Aminophosphazenes¹," Inorg.Chem. 21(1):515-521 (Jan. 1982).

ALLCOCK, H. R., et al., "Amphilphilic Polyphosphazenes as Membrane Materials: Influence of Side Group on Radiation Cross Linking," Biomaterials 9(6):500-508 (Nov. 1988).

ALLCOCK, H. R., et al., "Phosphonitrilic Compounds. IV. High Molecular Weight Poly[bis(amino)phosphazenes] and Mixed-Substituent Poly(aminophosphazenes)," Inorg. Chem. 11(11):2584-2590 (1972).

ALLCOCK, H. R., et al., "Polyphosphazenes with Etheric Side Groups: Prospective Biomedical and Solid Electrolyte Polymers," Macromolecules 19:1508-1512 (1986).

ALLCOCK & KWON, "An Ionically Cross-Linkable Polyphosphazene: Poly[bis(carboxylatophenoxy)phosphazene] and Its Hydrogels and Membranes," Macromolecules 22:75-79 (1989).

ALLCOCK & KWON, "Glyceryl Phosphazenes: Synthesis, Properties, and Hydrolysis," Macromolecules 21(7):1980-1985 (1988).

ALLCOCK & SCOPELIANOS, "Synthesis of Sugar-Substituted Cyclic and Polymeric Phosphazenes and Their Oxidation, Reduction, and Acetylation Reactions," Macromolecules 16(5):715-719 (1983).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

ANDERSON, et al., "Gene Expression in Implanted Rat Hepatocytes Following Retroviral-Mediated Gene Transfer," Somatic Cell & Mol. Gen., 15(3):215-227 (1989).

ANDERSON, Caltech Biology, 1987

ALBERTS, et al. Molecular Biology of The Cell Garland Publishing, Inc., pp 893-894

ATALA and CASALE, "Management of Primary Vesicoureteral Reflux," Infections in Urology pp 39-43 (March/April, 1990)

ATALA, et al., "Endoscopic Treatment of Vesicoureteral Reflux with a Chondrocyte-Alginate Suspension," The Journal of Urology 152:641-643 (August, 1994).

ATALA, et al., "Endoscopic Treatment of Vesicoureteral Reflux with a Self-Detachable Balloon System," The Journal of Urology 148:724-728 (August, 1992).

ATALA, et al., "Formation of Urothelial Structures in Vivo from Dissociated Cells Attached to Biodegradable Polymer Scaffolds in Vitro," The Journal of Urology 148:658-662 (August 1992).

ATALA, et al., "Implantation in Vivo and Retrieval of Artificial Structures Consisting of Rabbit and Human Urothelium and Human Bladder Muscle," The Journal of Urology 150:608-612 (August 1993).

ATALA, et al., "Injectable Alginate Seeded with Chondrocytes as a Potential Treatment for Vesicoureteral Reflux," The Journal of Urology 150:745-747 (August, 1993).

ATALA, et al., "Laparoscopic Correction of Vesicoureteral Reflux," The Journal of Urology 150:748-751 (August, 1993).

ATALA, et al., "Sonography with Sonicated Albumin in the Detection of Vesicoureteral Reflux," The Journal of Urology 150:756-758 (August, 1993).

ATALA, "Endoscopic Treatment of Reflux with Autologous Bladder Muscle Cells," American Academy of Pediatrics Meeting held in Dalls, TX 10/23/94 (Abstract)

ATALA, "Laparoscopic Treatment of Vesicoureteral Reflux," Dia. Ped. Urol. 14:212 (1993).

BAKLUND, et al. "Toward a Transplantation Therapy in Parkinson's Disease," Annals of the N.Y. Acad. of Sci. 495:658-673 (1987).

BAZEED, et al. "New Surgical Procedure for Management of Peyronie Disease," Urology 21(5), 501-504 (1983).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069
Filed: November 3, 1998
Issued: February 19, 2002
INFORMATION DISCLOSURE STATEMENT

BEN-ZE'EV, et al. "Cell-Cell and Cell-Matrix Interactions Differentially Regulate the Expression of Hepatic and Cytoskeletal Genes in Primary Cultures of Rat Hepatocytes," Proc. Natl. Acad. Sci. USA 85:2161-2165 (Apr. 1988).

BENNETT & HIRT, "A History of Tissue Expansion," Dermatol. Surg. Oncol. 19:1066-1073 (1993).

BERRINO, et al. "Surgical Correction of Breast Deformities Following Long-Lasting Complications of Polyurethane-Covered Implants," Ann. Plast. Surg., 24:481 (1990).

BIERS, "Organogenesis' Human Artery Equivalent May Revolutionize Vascular Grafts," Genetic Engineering News (Nov/Dec 1987).

BISSELL, et al., "Interactions of Rat Hepatocytes with Type IV Collagen, Fibronectin and Laminin Matrices, Distinct Matrix-Controlled Modes of Attachment and Spreading," European Journ. of Cell Biology 40:72-78 (1986).

BISSELL, et al. "The Role of Extracellular Matrix in Normal Liver," Scand. J. Gastroenterol., 23:107 (1988).

BISSELL, "Support of Cultured Hepatocytes by a Laminin-Rich Gel," J. Clin. Invest. 79:801-812 (1987).

BJORKLUND, Annals of the N.Y. Academy of Science 495:676-686 (1987).

BLAIVAS, et al., "When Sphincter Failure is the Cause of Female Stress Incontinence," Contemporary Urology 5(3):33-54 (March, 1993).

BOHN, et al., "Adrenal Medulla Grafts Enhance Recovery of Striatal Dopaminergic Fibers," Science 238(4817):913-916 (Aug.21, 1987).

"Brain Graft Seeks to Relieve Huntington Disease Patient," New York Times (March 4, 1988).

BREUER, et al., "Tissue Engineering Heart Valves," American Chemical Society Spring Meeting, (April 2-6, 1995).

BROWN, "Fibrin-Collagen Nerve Repair Device," Inventors: Russ Griffiths, Larry Stensaas & Ken Horsch, Letter dated May 10, 1988

BURKE, "The Effects of the Configuration of an Artificial Extracellular Matrix on the Development of a Functional Dermis," The Role of Extracellular Matrix in Development 351-355 (Alan R. Liss, Inc., NY 1984).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069
Filed: November 3, 1998
Issued: February 19, 2002
INFORMATION DISCLOSURE STATEMENT

CAO, et al., "Bone Reconstruction with Tissue Engineered Vascularized Bone,"
(Abstract) April 30 - May 3, 1995

CAO, et al., "The Generation of Neo-Tendon Using Synthetic Polymers seeded with
Tenocytes," Transplantation Proceedings, 26(6):3390-3392 (1994).

CHAIKIN, "Tissue Engineering: Science Non-Fiction," Medical Industry Executive pp
6-7 (May, 1993).

CHUANG, et al., "Sheath Needle for Liver Biopsy in High-Risk Patients," RSNA pp
261-262 (1988).

CILENTO, et al., "Phenotypic and Cytogenetic Characterization of Human Bladder
Urothelia Expanded in Vitro," Microbiology & Immunology 152:665-670 (August, 1994).

CLAES, et al., "Pulmonary Migration Following Periurethral Polytetrafluorethylene
Injection for Urinary Incontinence," The Journal of Urology 142:821-822 (September, 1989).

COHEN, "Navigating Through Tissue Expansion Terminology," J. Dermatol. Surg.
Oncol. 19:614-615 (1993).

COSIMI, et al., "Transplantation of Skin," Surgical Clinics of N.A. 58(2), 435-451
(April, 1978).

COLLIER, et al., "Norepinephrine Deficiency and Behavioral Senescence in Aged Rats:
Transplanted Locus Ceruleus Neurons as an Experimental Replacement Therapy," Annals of the
New York Academy of Science 495:396-403 (1987).

CULLITON, "Gore Tex Organoids and Genetic Drugs," Science 246:747-749 (1989).

DA SILVA, "An In Vivo Model to Quantify Motor and Sensory Peripheral Nerve
Regeneration Using Bioresorbable Nerve Guide Tubes," Brain Research, 342:307-315 (1985).

DAVIS., et al., "Human Amnion Membrane Serves as a Substratum for Growing Axons
in Vitro and in Vivo," Science, 236:1106-1109 (May 29, 1987).

DEL CERRO, et al., "Retinal Transplants into One Anterior Chamber of the Rat Eye,"
Neuroscience 21:(3)707-23 (June 1987).

DOILLON, et al., "Collagen-Based Wound Dressings: Control of the Pore Structure and
Morphology," Journal of Biomedical Materials Research, 20:1219-1228 (1986).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

DOILLON, et al., "Epidermal Cells Cultured on a Collagen-Based Material," G. W. Bailey, Editor, *Proceedings of the 44th Annual Meeting of the Electron Microscopy Society of America*, (1986).

EBATA, et al. "Liver Regeneration Utilizing Isolated Hepatocytes Transplanted into the Rat Spleen," Surg. Forum 29: 338-340 (1978).

ELKOWITZ, et al., "Various Methods of Breast Reconstruction After Mastectomy: An Economic Comparison," Plastic and Reconstructive Surgery, 92(1):77-83 (July 1993).

ERICKSON, "Material Help," Scientific American pp 114-116 (August, 1992).

FERRO, et al., "Periurethral Granuloma: Unusual Complication of Teflon Periurethral Injection," Urology 31(5):422-423 (May, 1988).

FOLKMAN, et al., "Angiogenic Factors," Science 235:442-447 (January 23, 1987).

FONTAINE, et al., "Optimization Studies on Retroviral Mediated Gene Transfer into Rat Hepatocytes: Implications for Gene Therapy," The Society of University Surgeons, Resident's Program, Cincinnati, Ohio (February 15, 1992).

FONTAINE, et al., "Transplantation of Genetically Altered Hepatocytes Using Cell-Polymer Constructs," Transplantation Proceedings, 25:1002-1004 (February 1993).

FRESHNEY, "The Culture Environment: I. Substrate, Gas Phase, and Temperature," Culture of Animal Cells pp55-56 (Alan R. Liss, NY 1983).

GASH, et al., "Amitotic Neuroblastoma Cells Used for Neural Implants in Monkeys," Science 233(4771):1420-2 (September 26, 1986).

GASH, "Neural Transplantation: Potential Therapy for Alzheimer's Disease," J. Neural Trans. [Suppl] 24:301-8 (1987).

GEISS, et al., "Multicenter Survey of Endoscopic Treatment of Vesidoureteral Reflux in Children," Eur. Urol 17:328-329 (1990).

GILBERT, et al., "Cell Transplantation of Genetically Altered Cells on Biodegradable Polymer Scaffolds in Syngeneic Rats," Transplantation, 56(2): 423-427 (August, 1993)..

GRANDE, et al., "Healing of Experimentally Produced Lesions in Articular Cartilage Following Chondrocyte Transplantation," The Anatomical Record 218:142-148 (1987).

GRANDE, et al., "The Repair of Experimentally Produced Defects in Rabbit Articular Cartilage by Autologous Chondrocyte Transplantation," (May 11, 1988).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

GREEN, "Growth of Cultured Human Epidermal Cells into Multiple Epithelia Suitable for Grafting," Proc. Natl. Acad. Sci. USA 76(11):5665-5668 (November, 1979).

GROLLEMAN, et al., "Studies on a Bioerodible Drug Carrier System Based on Polyphosphazene," Journal of Controlled Release 3:143-154 (1986).

GROTH, et al., "Correction of Hyperbilirubinemia in the Glucuronyltransferase-Deficient Rat by Intraportal Hepatocyte Transplantation," Transplant. Proc. 9:313-316 (1977).

HAMMOND, et al., "Morphologic Analysis of Tissue-Expander Shape Using a Biomechanical Model," Plastic and Reconstructive Surgery 92(2):255-259 (August, 1993).

HARRIS, et al. "Silicone Rubber Substrata: A New Wrinkle in the Study of Cell Locomotion," Science 208:177-179 (1980).

HENDREN & ATALA, "Use of Bowel for Vaginal Reconstruction," The Journal of Urology 152:752-755 (August, 1994).

HENLY, et al., "Particulate Silicone for Use in Periurethral Injections: A Study of Local Tissue Effects and a Search for Migration," The Journal of Urology 147(4):376A (April, 1992).

HENRY, et al., "Nerve Regeneration Through Biodegradable Polyester Tubes," Exp. Neurol. 90(3): 652-676 (December, 1985).

INGBER, et al., "Cells as Tensegrity Structures: Architectural Regulation of Histodifferentiation by Physical Forces Transduced Over Basement Membrane," Gene Expression During Normal and Malignant Differentiation, L. C. Anderson, et al., editors, pp 13-32 (Academic Press, Orlando, FL 1985).

INGBER, et al., "Endothelial Growth Factors and Extracellular Matrix Regulate DNA Synthesis Through Modulation of Cell and Nuclear Expansion," In Vitro Cellular and Developmental Biology 23(5):387-394 (May, 1987).

INGBER, et al., "Control of Capillary Morphogenesis: A Molecular System of Mechanical Switches," J. Cell Biol., 107:797a (1988).

INGBER, "How Does Extracellular Matrix Control Capillary Morphogenesis?" Cell 58:803-805 (September 8, 1989).

INGBER, "Growth Control Through Fibronectin-Dependent Modulation of Cell Shape,," J. Cell Biol. 105:219a (1987).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

INGBER, et al., "Mechanochemical Switching Between Growth Factor-Stimulated Angiogenesis In Vitro: Role of Extracellular Matrix," J. Cell. Biol., 109:317-330 (1989).

JACKSIC, et al., "The Use of 'Artificial Skin' for Burns," Ann. Rev. Med. 38:107-116 (1987).

JAUREGYU, et al., "Attachment and Long Term Survival of Adult Rat Hepatocytes in Primary Monolayer Cultures: Comparison of Different Substrata and Tissue Culture Medial Formulations," In Vitro Cellular & Development Biology, 22(1):13-22 (January 1986).

JONES, "Degradation of Artificial Tissue Substrates," Cancer Invasion and Metastasis: Biologic and Therapeutic Aspects, 177-185 (Raven Press, NY 1984).

JUNQUIERA, et al., 1989 Basic Histology, Prentice Hall, pp. 282-283 (1989).

KEHNA, et al., "Diffusion of Antibiotics Across Tissue Expanders: An in Vitro Study," Annals of Plastic Surgery 32(4):346-349 (April, 1994).

KLAGSBURN, "Large-Scale Preparation of Chondrocytes," Methods in Enzymology Vol. LVIII, Academic Press, New York, 1979

KLEINMAN, et al., "Use of Extracellular Matrix Components and Cell Culture," Analytical Biochemistry 166:1-13 (1987).

KLOMPMAKER, et al, "Porous Polymer Implants for Repair of Full-Thickness Defects of Articular Cartilage: An Experimental Study in Rabbit and Dog," Biomaterials 13(9):625-634 (1992).

KOLATA, "Parkinson Procedure: Fervor Turns to Disillusion," The New York Times, (April 21, 1988).

KORDOWER, et al., "An In Vivo and In Vitro Assessment of Differentiated Neuroblastoma Cells as a Source of Donor Tissue for Transplantation," Annals of The New York Academy of Sciences, 495:606-622 (new York 1987).

KORDOWER, et al., "Neuroblastoma Cells in Neural Transplants: A Neuroanatomical and Behavioral Analysis," Brain Research, 417:85-98 (1987).

KRETSCHMER, et al, "Autotransplantation of Pancreatic Fragments to the Portal Vein and Spleen of Total Pancreatectomized Dogs," Ann. Surg., 187:79-86 (January, 1978).

KUSANO, et al., Acta Japoni Hepato 63:345-351 (1989).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

LANGER & MOSES, "Biocompatible Controlled Release Polymers for Delivery of Polypeptides and Growth Factors," Journal of Cellular Biochemistry, 45:340-345 (1991).

LANGER and VACANTI, "Tissue Engineering," Science 260:920-926 (May 14, 1993).

LEONARD, et al., "Endoscopic Injection of Glutaraldehyde Cross-Linked Bovine Dermal Collagen for Correction of Vesidoureteral Reflux," The Journal of Urology 145:115-119 (January, 1991).

LEONG, et al., "Bioerodible Polyanhydrides as Drug-Carrier Matrices. I: Characterization, Degradation, and Release Characteristics," Journal of Biomedical Materials Research, 19:941-955 (1985).

LETOURNEAU, "Possible Roles of Cell-to-Sutstratus Adhesion in Neuronal Morphogenesis," Developmental Biology, 44:77-91 (1975).

LEWIN, "Cloud Over Parkinson's Therapy," Science News, 240: 390-392 (1988).

LEWIN, "Disappointing Brain Graft Results," Science, p. 1407 (June 10, 1988).

LI, et al., "Influence of a Reconstituted Basement Membrane and its Components of Casein Gene Expression and Secretion in Mouse Mammary Epithelial Cells," Proc. Natl. Acad. Sci. USA, 84:136-140 (1987).

LUCAS, et al, "Ectopic Induction of Cartilage and Bone by Water-Soluble Proteins from Bovine Bone Using a Ppolyanhydride Delivery Vehicle," Journal of Biomedical Materials Research 24(7):901-911 (1990).

MACKLIS, et al., "Cross-Linked Collagen Surface for Cell Culture that is Stable, Uniform, and Optically Superior to Conventional Surfaces," In Vitro Cellular & Developmental Biology, 21(3)(1): 189-194 (March 1985).

MADISON, et al., "Increased Rate of Peripheral Nerve Regeneration Using Bioresorbable Nerve Guides and Lamin-Containing Gel," Exp. Neurol., 88(3) 767-772 (June 1985).

MADISON, et al., "Nontoxic Nerve Guide Tubes Support Neovascular Growth in Transected Rat Optic Nerve," Exp. Neurol. 86:448-461 (1984).

MADISON, rt al. "Peripheral Nerve Regeneration with Entubulation Repair: Comparison of Biodegradable Nerve Guides Versus Polyethylene Tubes and the Effects of a Laminin-Containing Gel," Exp. Neurol. 95(2)387-390 (February, 1987).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

MALIZIA, et al., "Migration and Granulomatous Reaction After Periurethral Injection of Polytef (Teflon)," JAMA, 251(24):3277-3281 (June, 1984).

MARCIANO and GASH, "Structural and Functional Relationships of Grafted Vasopressin Neurons," Brain Res., 370(2):338-342 (April 9, 1986).

MATAS, et al., "Hepatocellular Transplantation for Metabolic Deficiencies: Decrease of Plasma Bilirubin in Gunn Rats," Science 192:892-894 (1976).

MATOUSCHEK, "Die Behandlung des vesikorenenalen Refluxes durth Transurethrale Einspritzung von Teflonpaste," Urologe A 20:263-264 (1981).

MESNIL, et al., "Cell Contact but Not Junctional Communication (Dye Coupling) with Biliary Epithelial Cells is Required for Hepatocytes to Maintain Differentiated Functions," Exper. Cell. Res. 173:524-533 (1987).

MICHAPOULOS & PITOT, "Primary Culture of Parenchymal Liver Cells on Collagen Membranes," Exper. Cell. Res. 94:70-78 (1975).

MILLARUELO, "Role of Plasminogen Activator and its Inhibitors in Axonal Outgrowth and Regeneration In Vivo," Caltech Biology, (1987).

MINATO, et al., "Transplantation of Hepatocytes for Treatment of Surgically Induced Acute Hepatic Failure in the Rat," Eur. Surg. Res., 16:162-169 (1984).

MITTLEMAN & MARRACCINI, "Pulmonary Teflon Granulomas Following Periurethral Teflon Injection for Urinary Incontinence," Arch. Pathol. Lab. Med. 107:611-612 (November 1983).

MITO, et al., "Hepatocellular Transplantation," Department of Surgery, Asahikawa Medical College 078 4-5 Nishi-Kagura, Asahikawa, Japan

MOONEY, "Control of Hepatocyte Function Through Polymer-Substrate Modulation," Thesis Proposal - Department of Chemical Engineering, Massachusetts Institute of Technology (September 22, 1989).

MOONEY, "Switching from Differentiation to Growth in Hepatocytes: Control by Extracellular Matrix," J. Cell. Phys. (151):497-505 (1992).

MOONEY, et al., "Induction of Hepatocyte Differentiation by the Extracellular Matrix and an RGD-Containing Synthetic Peptide," Mat. Res. Soc. Symp. Proc. 252 (1992).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

MOONEY, et al., "Integrating Cell Transplantation and Controlled Drug Delivery Technologies to Engineer Liver Tissue," (abstract) Materials Research Society, (April 17-21, 1995).

MOONEY, et al., "Tissue Engineering Using Cells and Synthetic Polymers," Transplantation Reviews, 7(3):153-162 (1993).

MOUNZER, et al., "Polyglycolic Acid Mesh in Repair of Renal Injury," Urology 28(2):172-130 (1986).

MOVITZ, "Accessory Spleens and Experimental Splenosis Principles of Growth," The Chicago Medical School Quarterly, 26(4):183-187 (Winter-Spring 1967).

NAHI, et al., "Successful Islet Transplantation in Spontaneous Diabetes," Surgery 86:218-226 (1979)

NASTELIN, "Pancreatic Islet Cell Transplantation: Optimization of Islet Cell Adhesion by Altering Polymer Surface Characteristics," Harvard-M.I.T. Division of Health Sciences and Technology (February 1990).

NAUGHTON, et al., "Granulopoiesis and Colony Stimulating Factor Production in Regenerating Liver," Exp. Hematol., 10(5):451-458 (May, 1982).

NAUGHTON, et al., "Long-Term Growth of Rat Bone Marrow Cells in a Three-Dimensional Matrix," Medical Laboratory Sciences Department, Hunter College School of Health Sciences, New York, The Anatomical Record, 218(1):97a (May, 1987).

NAUGHTON, et al., "Erythropoietin Production by Macrophages in the Regenerating Liver," Journal of Surgical Oncology 30:184-197 (1985).

NOTTER, et al, "Neuronal Properties of Monkey Adrenal Medulla in vitro," Cell Tissue Res., 244(1):69-76 (1986).

NYILAS, et al, "Peripheral Nerve Repair with Bioresorbable Prosthesis," Trans. Am. Soc. Artif. Intern. Organs, 29:307-313 (1983).

O'C. HAMILTON, "Miracle Cures May be in Your Cells," BusinessWeek (December 6, 1993).

O'CONNOR, et al., "Grafting of Burns with Cultured Epithelium Prepared from Autologous Epidermal Cells," The Lancet, I(8210):75-78 (January, 1981).

O'DONELL & PURI, "Treatment of Vesicoureteric Reflux by Endoscopic Injection of Teflon," British Medical Journal 289:7-9 (July 7, 1984).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

OELLRICH, R. G., et al. "Biliary Atresia," Neonatal Network pp 25-30 (April, 1987).

OLIWENSTEIN, "The Power of Plastics," Discover p. 18 (December, 1989).

OMERY, "A Nursing Perspective of the Ethical Issues Surrounding Liver Transplantation," Heart & Lung 17(6):626-630 (November, 1988).

PAIGE, et al., "De Novo Cartilage Generation Using Calcium Alginate-Chondrocyte Constructs," Children's Hospital, Boston, MA, Plastic Surgery Research Council Meeting; N.E. Society of Plastic and Reconstructive Surgeons Meeting; and North Eastern Society of Plastic Surgeons Meeting pp 1-34 (1993).

PASIK, Annals of the N.Y. Academy of Science, 495:674-675 (1987).

PATTERSON, et al., "Adrenal Chromaffin Cell-Derived Cholinergic Neurons for Brain Transplants," Caltech Biology pp 201-202 (1987).

PERLOW, M. J., "Brain Grafting as a Treatment for Parkinson's Disease," Neurosurgery 20(2):335-342 (1987).

PIMPL, et al., "Experimentelle Studie zur Frage der Transplantatkoniditionierung und Transplantatgrofe bei heterotoper autologer Milztransplantation," Lagenbecks Archiv 37215-36218 (Salzburg 1984).

PIMPL, et al., "Perfusion of Autologous Splenic Grafts in Correlation with Specific Immunological Functions An Experimental Study in Pigs," Eur. Surg. Res. 19:53-61 (1987).

PITMAN, et al., "The Use of Adhesives in Chondrocyte Transplantation Surgery: In-Vivo Studies," Bulletin of the Hospital for Joint Diseases Orthopaedic Institute 49(2):213-220 (1989).

PTASINSKA-URBANSKA, et al, "Intrascleral Introduction of Isolated Allogeneic Chondrocytes Capable of Cartilage Reformation in Rabbits; Possible Procedure in Treatment of Detachment of the Retina," Exp. Eve. Res., 24(3):241-247 (1977).

PUELACHER, W. C., et al., "Tissue-Engineered Growth of Cartilage: the Effect of Varying the Concentration of Chondrocytes Seeded onto Synthetic Polymer Matrices," Int. J. Oral Maxillofac. Surg., 23:49-53 (1994).

RAMES & AARTONSON, "Migration of Polytef Paste to the Lung and Brain Following Intravesical Injection for the Correction of Reflux," Pediatric Surgery 6(1):239-240 (January, 1991).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

REDMOND, et al., "Fetal Neuronal Grafts in Monkeys Given Methyphenyltetrahydropyridine," The Lancet, pp 1125-1127 (May 17, 1986).

REDMOND, et al., "Transplants of Primate Neurons," The Lancet, 2(8510):1046 (November 1, 1986).

REID, et al. "Long-Term Cultures of Normal Rat Hepatocytes on Liver Biomatrix," Ann. NY Acad. Sci. 349:70-76 (1980)

RETIK, et al., "Management of Severe Hypospadias with a 2-Stage Repair," Microbiology & Immunology 152:749-751 (August, 1984).

RHINE, et al., "Polymers for Sustained Macromolecule Release: Procedures to Fabricate Reproducible Delivery Systems and Control Release Kinetics," Journal of Pharmaceutical Sciences, 69(3):265-269 (March, 1980).

ROSEN, "Bioerodible Polymers for Controlled Release Systems," Controlled Release Systems: Fabrication Technology, II:83-110

ROSEN, "Bioerodible Polyanhydrides for Controlled Drug Delivery," 1983 Butterworth & Co. (Publishers) Ltd.

SAPOZHNIKOVA, et al., "Morphological Changes in Splenic Autografts Following Splenectomy: Experimental and Clinical Findings," Biological Abstracts, 86(76896) (1987).

SASAKI, "Neovascularization in the Splenic Autograft Transplanted into Rat Omentum as Studied by Scanning Electron Microscopy of Vascular Casts," Virchows Arch., 409:325-334 (1986).

SAWADA, et al., "Effects of Extracellular Matrix Components on the Growth and Differentiation of Cultured Rat Hepatocytes," In Vitro Cellular & Development Biology, 23(4): 267-273 (April, 1987).

SCHMECK, "Doctors try to Capitalize on the Liver's Ability to Regenerate Itself," The New York Times Medical Science, (May 16, 1989).

SCHUBERT & BAIRD, "Multiple Influences of a Heparin-Binding Growth Factor for Neuronal Development," The Journal of Cell Biology, 104:635-643 (March 1987).

SECKLE, "Nerve Regeneration Through Synthetic Biodegradable Nerve Guides: Regulation by the Target Organ," Plast. Reconstr. Surg., 74(2):173-81 (August, 1974).

SELDEN, et al., "The Pulmonary Vascular Bed as a Site for Implantation of Isolated Liver Cells in Inbred Rats," Transplantation, 38(1):81-83 (July, 1984).

SHINE, et al., "Cultured Peripheral Nervous System Cells Support Peripheral Nerve Regeneration Through Tubes in the Absence of Distal Nerve Stump," Journal of Neuroscience Research, 14:393-401 (1985).

SIEGEL & LANGER, "Controlled Release of Polypeptides and Other Macromolecules," Pharmaceutical Research, pp 2-10 (1984).

SIRICA, et al., "Fetal Phenotypic Expression by Adult Rat Hepatocytes on Collagen Gel/Nylon Meshes," Proc. Natl. Acad. Sci. USA, 76(1):283-287 (January, 1979).

SIRICA, A., et al, "Use of Primary Cultures of Adult Rat Hepatocytes on Collagen Gel-Nylon Mesh to Evaluate Carcinogen-Induced Unscheduled DNA Synthesis," Cancer Research, 40:3259-3267 (September 1980).

SLADEK, et al, "Reversal of Parkinsonism by Fetal Nerve Cell Transplants in Primate Brain," Annals of the New York Academy of Sciences, 495:641-657 (1987).

SLADEK, et al., "Survival and Growth of Fetal Catecholamine Neurons Transplanted Into Primate Brain," Brain Research Bulletin, 17:809-818 (1986).

SLADEK & SHOULSON, "Neural Transplantation: A Call for Patience Rather Than Patients," Science, 240:386-388 (June 10, 1988).

SLADEK, "Transplantation of Fetal Dopamine Neurons in Primate Brain Reverses MPTP Induced Parkinsonism," Progress in Brain Research, 71:309-323 (1987).

SOMMER, et al., "Hepatocellular Transplantation for Treatment of D-Galactosamine-Induced Acute Liver Failure in Rats," Transplant. Proc., 11(1):578-584 (March, 1979).

STEIN, "Three Dimensional Tissue Reorganization in Hepatocyte Transplantation," American College of Surgeons, Surgical Forum, (October, 1991).

STEMPLE, Altech Biology (1987).

STROM, et al., "Isolation, Culture, and Transplantation of Human Hepatocytes," JNCL, 68(5):771-778 (May 1982).

SUDHAKARAN, et al., "Modulation of Protein Synthesis and Secretion by Substratum in Primary Cultures of Rat Hepatocytes," Exper. Cell Res. 167:505-516 (1986).

SULLIVAN, "Spinal Injury Research Yields a Glimmer of Hope," The New York Times p.C6 (July 14, 1987).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

SUTHERLAND, D. E., et al., "Hepatocellular Transplantation in Acute Liver Failure," Surgery 82(1):124-132 (July 1977).

TACHIBANA, "Ureteral Replacement Using Collagen Sponge Tube Grafts," The Journal of Urology 133(4):866-869 (April, 1985).

TAKEDA, et al., "Hepatocyte Transplantation in Biodegradable Polymer Scaffolds Using the Dalmatian Dog Model of Hyperuricosuria," Transplantation Proceedings 27(1):635-636 (February, 1995).

TAVASSOLI, et al., "Studies on Regeneration of Heterotopic Splenic Autotransplants," Blood, 41(5):701-709 (May, 1973).

THOMPSON, J. A., "Heparin-Binding Growth Factor 1 Induces the Formation of Organoid Neovascular Structures in Vivo," Proc. Natl. Acad. Sci USA, 86:7928-27932 (October, 1989).

THOMPSON, "Implantable Bioreactors: Modern Concepts of Gene Therapy," Current Communications in Molecular Biology, Daniel Marshak, et al., editors, pp 143-147 (Cold Spring Harbor Laboratory, 1989).

THUROFF, et al., "Cultured Rabbit Vesical Smooth Muscle Cells for Lining of Dissolvable Synthetic Prosthesis," Urology, 21(2):155-158 (1983).

TOMOMURA, et al, "The Control of DNA Synthesis in Primary Cultures of Hepatocytes From Adult and Young Rats: Interactions of Extracellular Matrix Components, Epidermal Growth Factor, and the Cell Cycle," ©1987 Alan R. Liss, Inc.

Unipoint Industries, Inc., "Polyvinyl Alcohol Foam for Surgical And Industrial Use," Product Review

UNOS Update, "National Cooperative Transplantation Study Completed," 7(10) (October/November 1991).

UPTON, et al., "Neocartilage Derived from Transplanted Perichondrium: What is it?" Plastic and Reconstructive Surgery 68(2): 166-174 (1981).

UYAMA, et al., "Delivery of Whole Liver-Equivalent Hepatocyte Mass Using Polymer Devices and Hepatotrophic Stimulation," Transplantation 55:932-935 (April, 1993).

VACANTI, et al., "Formation of New Cartilage in Vivo by Implantation of Cell-Polymer Constructs Created in Vitro,"

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

VACANTI, et al., "Synthetic Polymers Seeded with Chondrocytes Provide a Template for New Cartilage Formation," Journal of the American Society of Plastic and Reconstructive Surgeons, Inc., 88(5):753-759 (November 1991).

VACANTI, "Tissue Engineered Composites of Bone and Cartilage Using Synthetic Polymers Seeded with Two Cell Types," 39th Annual Meeting of the Orthopaedic Research Society (February 15-18, 1993).

VACANTI, "Beyond Transplantation," Arch. Surgery 123:545-549 (May 1988).

VACANTI, et al., "Engineered Bone from Polyglycolic Acid Polymer Scaffold and Periosteum," (abstract) Materials Research Society, (April 17-21, 1985).

VACANTI, J.P., et al., "Selective Cell Transplantation Using Bioabsorbable Artificial Polymers as Matrices," Journal of Pediatric Surgery, 23(1):3-9 (January 1988).

VAN DER KWAST, et al., "Establishment and Characterization of Long-Term Primary Mouse Urothelial Cell Cultures," Urological Research, 17(1):290-293 (1989).

VARGO, "Infection as a Complication of Liver Transplant," Critical Care Nurse 9(4):52-62

VIJG, et al., "UV-Induced DNA Excision Repair in Rat Fibroblasts During Immortalization and Terminal Differentiation in Vitro," Exp. Cell. Res. 167:517-530 (1986).

VORSTMAN, et al., "Polytetrafluoroethylene Injection for Urinary Incontinence in Children," The Journal of Urology 133(2):248-250 (February, 1985).

VROEMEN, et al., "Hepatocyte Transplantation for Enzyme Deficiency Disease in Congenic Rats," Transplantation, 42(2):130-135 (1986).

WALKER, et al., "Injectable Bioglass as a Potential Substitute for Injectable Polytetrafluoroethylene," The Journal of Urology 148(1):645-647

WALTON, et al., "Tissue Engineering of Biomaterials for Composite Reconstruction: An Experimental Model," Annals of Plastic Surgery 30(2):104-110 (February, 1993).

WHITAKER, "Scientists Growing Tissue From 'Seed'," The Boston Globe (Monday, February 22, 1993).

WOZNEY, et al., "Novel Regulators of Bone Formation: Molecular Clones and Activities," Science, 242:1528-1534 (December 16, 1988).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069

Filed: November 3, 1998

Issued: February 19, 2002

INFORMATION DISCLOSURE STATEMENT

YANNAS, et al., "Design of an Artificial Skin. I. Basic Design Principles," Journal of Biomedical Materials Research 14:65-81 (1980).

YANNAS, et al., "Regeneration of Sciatic Nerve Across 15 mm Gap by Use of a Polymeric Template," Polym. Sci. Technol. Iss. Adv. Biomed. Polymer 35:109 (1987).

YANNAS, et al., "Artificial Skin: A Fifth Route to Organ Repair and Replacement," Iss. Polym. Biomaterial, 106:221-230 (1986).

YANNAS, et al., "Polymeric Template Facilitates Regeneration of Sciatic Nerve Across 15 MM Gap," Polymer. Material Sci. Eng. 53:216-218 (1985).

YANNAS, et al., "Suppression of in Vivo Degradability and of Immunogenicity of Collagen by Reaction with Glycosaminoglycans," Polymer. Prepar. Am. Chem. Soc. Div. Polym. Chem., 16(2): 209-214 (1975).

YANNAS, "Wound Tissue Can Utilize a Polymeric Template to Synthesize a Functional Extension of Skin," Science 215:174-176 (1982).

YANNAS, "What Criteria Should be Used for Designing Artificial Skin Replacement and How Well do the Current Grafting Materials Meet These Criteria?" J. of Trauma, 24(9):S29-S39 (1984).

Report of the International Reflux Study Committee, "Medical Versus Surgical Treatment of Primary Vesicoureteral Reflux: A Prospective International Reflux Study in Children," The Journal of Urology 125:277-283 (March, 1981).

ZUND, et al., "A New Approach for a Bioprothetic-Heart Valve," The European Association for Cardio-Thoracic Surgery, (January 31, 1995).

Serial No.: 09/185,360 now U.S. Patent No. 6,348,069
Filed: November 3, 1998
Issued: February 19, 2002
INFORMATION DISCLOSURE STATEMENT

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

Date: February 19, 2004

HOLLAND & KNIGHT LLP
One Atlantic Center, Suite 2000
1201 West Peachtree Street
Atlanta, Georgia 30309-3400
(404) 817-8514
(404) 817-8588 (Fax)

580489_v1



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete If Known	
		Application Number	09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002
		Filing Date	November 3, 1998
		First Named Inventor	Joseph P. Vacanti
		Group Art Unit	3738
		Examiner Name	D. Isabella
Sheet 1 of 27	Attorney Docket Number	MIT 6917 (CMCC 450) DIV	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		1,995,970		Dorough	03-26-1935	
		2,609,347		Wilson	09-02-1952	
		2,653,917		Hammon	09-29-1953	
		2,659,935		Hammon	11-24-1953	
		2,664,366		Wilson	12-29-1953	
		2,676,945		Higgins	04-27-1954	
		2,683,136		Higgins	07-06-1954	
		2,703,316		Schneider	03-01-1955	
		2,758,987		Salzberg	08-14-1956	
		2,846,407		Wilson	08-05-1958	
		2,951,828		Zeile, et al.	09-06-1960	
		3,514,791		Sparks	06-02-1970	
		3,531,561		Trehu	09-29-1970	
		3,826,241		Bucalo	07-30-1974	
		3,880,991		Yolles	04-29-1975	
		3,883,393		Knazek, et al.	05-13-1975	
		3,902,497		Casey	09-02-1975	
		3,935,065		Doerig	01-27-1976	
		3,949,073		Daniels, et al.	04-06-1976	
		3,960,150		Hussain, et al.	06-01-1976	
		3,974,526		Dardik, et al.	08-17-1976	
		3,992,725		Homsy	11-23-1976	
		3,995,444		Clark, et al.	12-07-1976	
		4,026,304		Levy	05-31-1977	
		4,060,081		Yannas, et al.	11-29-1977	
		4,069,307		Higuchi, et al.	01-17-1978	
		4,137,921		Okuzumi	02-06-1979	
		4,141,087		Shalaby, et al.	02-27-1979	

Examine Signature		Date Considered	
-------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known	
			Application Number	
			09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002	
			Filing Date	
			November 3, 1998	
			First Named Inventor	
			Joseph P. Vacanti	
			Group Art Unit	
			3738	
			Examiner Name	
			D. Isabella	
Sheet			Attorney Docket Number	
2 of 27			MIT 6917 (CMCC 450) DIV	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		4,144,126		Burbidge	03-13-1979	
		4,186,448		Brekke	02-05-1980	
		4,192,827		Mueller, et al.	03-11-1980	
		4,205,399		Shalaby, et al.	06-03-1980	
		4,228,243		Iizuka	10-14-1980	
		4,239,664		Teag, et al.	12-16-1980	
		4,243,775		Rosensaft, et al.	01-06-1981	
		4,277,582		Mueller, et al.	07-07-1981	
		4,280,954		Yannas, et al.	07-28-1981	
		4,304,591		Mueller, et al.	12-08-1981	
		4,304,866		Green, et al.	12-08-1981	
		4,328,204		Wasserman, et al.	05-04-1982	
		4,347,847		Usher	09-07-1982	
		4,348,329		Chapman	09-07-1982	
		4,352,883		Lim	10-05-1982	
		4,356,261		Kuettner	10-26-1982	
		4,391,797		Folkman, et al.	07-05-1983	
		4,416,986		Markus, et al.	11-22-1983	
		4,427,808		Stol, et al.	01-24-1984	
		4,431,428		Schmer	02-14-1984	
		4,438,198		Schmer	03-20-1984	
		4,439,152		Small	03-27-1984	
		4,440,921		Allcock, et al.	04-03-1984	
		4,444,887		Hoffmann	04-24-1984	
		4,446,229		Indech	05-01-1984	
		4,446,234		Russo, et al.	05-01-1984	
		4,450,150		Sidman	05-22-1984	
		4,456,687		Green	06-26-1984	

Examine Signature		Date Considered	
------------------------------	--	------------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>		Complete if Known			
		Application Number	09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002		
		Filing Date	November 3, 1998		
		First Named Inventor	Joseph P. Vacanti		
		Group Art Unit	3738		
		Examiner Name	D. Isabella		
Sheet	3	of	27	Attorney Docket Number	MIT 6917 (CMCC 450) DIV

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		4,458,678		Yannas, et al.	07-10-1984	
		4,485,096		Bell	11-27-1984	
		4,485,097		Bell	11-27-1984	
		4,489,056		Himmelstein, et al.	12-18-1984	
		4,494,385		Kuraoka, et al.	01-22-1985	
		4,495,174		Allcock, et al.	01-22-1985	
		4,505,266		Yannas, et al.	03-19-1985	
		4,520,821		Schmidt, et al.	06-04-1985	
		4,528,265		Becker	07-09-1985	
		4,544,516		Hughes, et al.	10-01-1985	
		4,545,082		Hood	10-08-1985	
		4,553,272		Mears	11-19-1985	
		4,559,298		Fahy	12-17-1985	
		4,559,304		Kasai, et al.	12-17-1985	
		4,563,350		Nathan, et al.	01-07-1986	
		4,563,489		Urist	01-07-1986	
		4,563,490		Stol, et al.	01-07-1986	
		4,576,608		Homsy	03-18-1986	
		4,595,713		St. John	06-17-1986	
		4,609,551		Caplan, et al.	09-02-1986	
		4,627,853		Campbell, et al.	12-09-1986	
		4,637,931		Schmitz	01-20-1987	
		4,642,120		Nevo, et al.	02-10-1987	
		4,645,669		Reid	02-24-1987	
		4,675,189		Kent, et al.	06-23-1987	
		4,675,284		Levy, et al.	06-23-1987	
		4,681,763		Nathanson, et al.	07-21-1987	
		4,689,293		Goosen, et al.	08-25-1987	

Examine Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p align="center">Substitute for form 1449A/PTO</p> <p align="center">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p align="center">(use as many sheets as necessary)</p>				Complete if Known	
				Application Number	09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002
				Filing Date	November 3, 1998
				First Named Inventor	Joseph P. Vacanti
				Group Art Unit	3738
				Examiner Name	D. Isabella
Sheet	5	of	27	Attorney Docket Number	MIT 6917 (CMCC 450) DIV

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		AU	24245/88	B		02-13-1989		
		DE	35 18 150			10-23-1986		
		DE	28 53 614			07-26-1979		
		JP	62 011 459			01-20-1987		
		JP	63 074 498			04-04-1988		
		JP	63 196 273			08-15-1988		
		JP	63 196 595			08-15-1988		
		EP	0 153 896			09-04-1985		
		EP	0 282 746			09-21-1988		
		EP	0 339 607			11-02-1989		
		EP	0 226 061			06-24-1987		
		EP	0 248 246			06-02-1986		
		EP	0 248 247			06-02-1986		
		EP	0 361 957			09-29-1989		
		EP	0 344 924			05-05-1989		
		WO	87/06120			10-22-1987		
		WO	88/03785			06-02-1988		
		WO	89/00413			01-26-1989		
		WO	89/07944			09-08-1989		
		WO	90/12603			11-01-1990		
		WO	90/12604			11-01-1990		
		WO	91/01720			02-21-1991		
		WO	94/21299			09-24-1994		
		WO	92/06702			04-30-1992		
		WO	92/07525			05-14-1992		

Examine Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p align="center">Substitute for form 1449A/PTO</p> <p align="center">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p align="center">(use as many sheets as necessary)</p>				Complete If Known		
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002
				Filing Date		November 3, 1998
				First Named Inventor		Joseph P. Vacanti
				Group Art Unit		3738
				Examiner Name		D. Isabella
Sheet	6	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁸
		Office. ³	Number ²	Kind Code ⁵ (if known)				
		WO	93/07913			04-29-1993		
		WO	93/08850			05-13-1993		
		WO	93/16687			09-02-1993		
		WO	94/25079			11-10-1994		

OTHER ART -- NON PATENT LITERATURE DOCUMENTS				
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published		T ²
		ALLCOCK, H. R., et al., "Synthesis of Poly[(Amino Acid Alkyl Ester)Phosphazenes] ¹⁻³ ," <u>Macromolecules</u> , 10(4) (July/August, 1977).		
		ALLCOCK, H. R., et al., "Hydrolysis Pathways for Aminophosphazenes ¹ ," <u>Inorg.Chem.</u> 21(1):515-521 (Jan. 1982).		
		ALLCOCK, H. R., et al., "Amphilphilic Polyphosphazenes as Membrane Materials: Influence of Side Group on Radiation Cross Linking," <u>Biomaterials</u> 9(6):500-508 (Nov. 1988).		
		ALLCOCK, H. R., et al., "Phosphonitrilic Compounds. IV. High Molecular Weight Poly[bis(amino)phosphazenes] and Mixed-Substituent Poly(aminophosphazenes)," <u>Inorg. Chem.</u> 11(11):2584-2590 (1972).		
		ALLCOCK, H. R., et al., "Polyphosphazenes with Etheric Side Groups: Prospective Biomedical and Solid Electrolyte Polymers," <u>Macromolecules</u> 19:1508-1512 (1986).		

Examiner's Signature		Date Considered	
-------------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete If Known			
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002	
				Filing Date		November 3, 1998	
				First Named Inventor		Joseph P. Vacanti	
				Group Art Unit		3738	
				Examiner Name		D. Isabella	
Sheet	7	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		ALLCOCK & KWON, "An Ionically Cross-Linkable Polyphosphazene: Poly[bis(carboxylatophenoxy)phosphazene] and Its Hydrogels and Membranes," <u>Macromolecules</u> 22:75-79 (1989).	
		ALLCOCK & KWON, "Glyceryl Phosphazenes: Synthesis, Properties, and Hydrolysis," <u>Macromolecules</u> 21(7):1980-1985 (1988).	
		ALLCOCK & SCOPELIANOS, "Synthesis of Sugar-Substituted Cyclic and Polymeric Phosphazenes and Their Oxidation, Reduction, and Acetylation Reactions," <u>Macromolecules</u> 16(5):715-719 (1983).	
		ATALA and CASALE, "Management of Primary Vesicoureteral Reflux," <u>Infections in Urology</u> pp 39-43 (March/April, 1990)	
		ATALA, et al., "Endoscopic Treatment of Vesicoureteral Reflux with a Chondrocyte-Alginate Suspension," <u>The Journal of Urology</u> 152:641-643 (August, 1994).	
		ATALA, et al., "Endoscopic Treatment of Vesicoureteral Reflux with a Self-Detachable Balloon System," <u>The Journal of Urology</u> 148:724-728 (August, 1992).	
		ATALA, et al., "Formation of Urothelial Structures in Vivo from Dissociated Cells Attached to Biodegradable Polymer Scaffolds in Vitro," <u>The Journal of Urology</u> 148:658-662 (August 1992).	
		ATALA, et al., "Implantation in Vivo and Retrieval of Artificial Structures Consisting of Rabbit and Human Urothelium and Human Bladder Muscle," <u>The Journal of Urology</u> 150:608-612 (August 1993).	
		ATALA, et al., "Injectable Alginate Seeded with Chondrocytes as a Potential Treatment for Vesicoureteral Reflux," <u>The Journal of Urology</u> 150:745-747 (August, 1993).	
		ATALA, et al., "Laparoscopic Correction of Vesicoureteral Reflux," <u>The Journal of Urology</u> 150:748-751 (August, 1993).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known			
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002	
				Filing Date		November 3, 1998	
				First Named Inventor		Joseph P. Vacanti	
				Group Art Unit		3738	
				Examiner Name		D. Isabella	
Sheet	8	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		ATALA, et al., "Sonography with Sonicated Albumin in the Detection of Vesicoureteral Reflux," <u>The Journal of Urology</u> 150:756-758 (August, 1993).	
		ATALA, "Endoscopic Treatment of Reflux with Autologous Bladder Muscle Cells," American Academy of Pediatrics Meeting held in Dalls, TX 10/23/94 (Abstract).	
		ATALA, "Laparoscopic Treatment of Vesisoureteral Reflux," <u>Dia. Ped. Urol.</u> 14:212 (1993).*	
		BAKLUND, et al. "Toward a Transplantation Therapy in Parkinson's Disease," <u>Annals of the N.Y. Acad. of Sci.</u> 495:658-673 (1987).	
		BAZEED, et al. "New Surgical Procedure for Management of Peyronie Disease," <u>Urology</u> 21(5), 501-504 (1983).	
		BENNETT & HIRT, "A History of Tissue Expansion," <u>Dermatol. Surg. Oncol.</u> 19:1066-1073 (1993).	
		BEN-ZE'EV, et al. "Cell-Cell and Cell-Matrix Interactions Differentially Regulate the Expression of Hepatic and Cytoskeletal Genes in Primary Cultures of Rat Hepatocytes," <u>Proc. Natl. Acad. Sci. USA</u> 85:2161-2165 (Apr. 1988).	
		BERRINO, et al. "Surgical Correction of Breast Deformities Following Long-Lasting Complications of Polyurethane-Covered Implants," <u>Ann. Plast. Surg.</u> 24:481 (1990).	
		BIERS, "Organogenesis' Human Artery Equivalent May Revolutionize Vascular Grafts," <u>Genetic Engineering News</u> (Nov/Dec 1987).	
		BISSELL, et al. "The Role of Extracellular Matrix in Normal Liver," <u>Scand. J. Gastroenterol.</u> 23:107 (1988).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete If Known	
		Application Number Filing Date First Named Inventor Group Art Unit Examiner Name Attorney Docket Number	09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002 November 3, 1998 Joseph P. Vacanti 3738 D. Isabella MIT 6917 (CMCC 450) DIV
Sheet	9	of	27

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		BISSELL, et al., "Interactions of Rat Hepatocytes with Type IV Collagen, Fibronectin and Laminin Matrices, Distinct Matrix-Controlled Modes of Attachment and Spreading," <u>European Journ. of Cell Biology</u> 40:72-78 (1986).	
		"Brain Graft Seeks to Relieve Huntington Disease Patient," <u>New York Times</u> (March 4, 1988).	
		BISSELL, "Support of Cultured Hepatocytes by a Laminin-Rich Gel," <u>J. Clin. Invest.</u> 79:801-812 (1987).	
		BJORKLUND, <u>Annals of the N.Y. Academy of Science</u> 495:676-686 (1987).	
		BLAIVAS, et al., "When Sphincter Failure is the Cause of Female Stress Incontinence," <u>Contemporary Urology</u> 5(3):33-54 (March, 1993).	
		BOHN, et al., "Adrenal Medulla Grafts Enhance Recovery of Striatal Dopaminergic Fibers," <u>Science</u> 238(4817):913-916 (Aug.21, 1987).	
		BREUER, et al., "Tissue Engineering Heart Valves," American Chemical Society Spring Meeting, (April 2-6, 1995).	
		BROWN, "Fibrin-Collagen Nerve Repair Device," Inventors: Russ Griffiths, Larry Stensaas & Ken Horch, Letter dated May 10, 1988	
		BURKE, "The Effects of the Configuration of an Artificial Extracellular Matrix on the Development of a Functional Dermis," <u>The Role of Extracellular Matrix in Development</u> 351-355 (Alan R. Liss, Inc., NY 1984).	
		CAO, et al., "Bone Reconstruction with Tissue Engineered Vascularized Bone," (Abstract) April 30 - May 3, 1995	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p align="center">Substitute for form 1449A/PTO</p> <p align="center">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p align="center">(use as many sheets as necessary)</p>				Complete if Known		
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002
				Filing Date		November 3, 1998
				First Named Inventor		Joseph P. Vacanti
				Group Art Unit		3738
				Examiner Name		D. Isabella
Sheet	10	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		CAO, et al., "The Generation of Neo-Tendon Using Synthetic Polymers seeded with Tenocytes," <u>Transplantation Proceedings</u> , 26(6):3390-3392 (1994).	
		CHAIKIN, "Tissue Engineering: Science Non-Fiction," <u>Medical Industry Executive</u> pp 6-7 (May, 1993).	
		CHUANG, et al., "Sheath Needle for Liver Biopsy in High-Risk Patients," <u>RSNA</u> pp 261-262 (1988).	
		CILENTO, et al., "Phenotypic and Cytogenetic Characterization of Human Bladder Urothelia Expanded in Vitro," <u>Microbiology & Immunology</u> 152:665-670 (August, 1994).	
		CLAES, et al., "Pulmonary Migration Following Periurethral Polytetrafluorethylene Injection for Urinary Incontinence," <u>The Journal of Urology</u> 142:821-822 (September, 1989).	
		COHEN, "Navigating Through Tissue Expansion Terminology," <u>J. Dermatol. Surg. Oncol.</u> 19:614-615 (1993).	
		COSIMI, et al., "Transplantation of Skin," <u>Surgical Clinics of N.A.</u> 58(2), 435-451 (April, 1978).	
		COLLIER, et al., "Norepinephrine Deficiency and Behavioral Senescence in Aged Rats: Transplanted Locus Ceruleus Neurons as an Experimental Replacement Therapy," <u>Annals of the New York Academy of Science</u> 495:396-403 (1987).	
		CULLITON, "Gore Tex Organoids and Genetic Drugs," <u>Science</u> 246:747-749 (1989).	
		DA SILVA, "An In Vivo Model to Quantify Motor and Sensory Peripheral Nerve Regeneration Using Bioresorbable Nerve Guide Tubes," <u>Brain Research</u> , 342:307-315 (1985).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number 09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002		
			Filing Date November 3, 1998		
			First Named Inventor Joseph P. Vacanti		
			Group Art Unit 3738		
			Examiner Name D. Isabella		
Sheet	11	of	27	Attorney Docket Number MIT 6917 (CMCC 450) DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		DAVIS, et al., "Human Amnion Membrane Serves as a Substratum for Growing Axons in Vitro and in Vivo," <u>Science</u> , 236:1106-1109 (May 29, 1987).	
		DEL CERRO, et al., "Retinal Transplants into One Anterior Chamber of the Rat Eye," <u>Neuroscience</u> 21:(3)707-23 (June 1987).	
		DOILLON, et al., "Collagen-Based Wound Dressings: Control of the Pore Structure and Morphology," <u>Journal of Biomedical Materials Research</u> , 20:1219-1228 (1986).	
		DOILLON, et al., "Epidermal Cells Cultured on a Collagen-Based Material," G. W. Bailey, Editor, <u>Proceedings of the 44th Annual Meeting of the Electron Microscopy Society of America</u> , (1986).	
		EBATA, et al. "Liver Regeneration Utilizing Isolated Hepatocytes Transplanted into the Rat Spleen," <u>Surg. Forum</u> 29: 338-340 (1978).	
		ELKOWITZ, et al., "Various Methods of Breast Reconstruction After Mastectomy: An Economic Comparison," <u>Plastic and Reconstructive Surgery</u> , 92(1):77-83 (July 1993).	
		ERICKSON, "Material Help," <u>Scientific American</u> pp 114-116 (August, 1992).	
		FERRO, et al., "Periurethral Granuloma: Unusual Complication of Teflon Periurethral Injection," <u>Urology</u> 31(5):422-423 (May, 1988).	
		FOLKMAN, et al., "Angiogenic Factors," <u>Science</u> 235:442-447 (January 23, 1987).	
		FONTAINE, et al., "Optimization Studies on Retroviral Mediated Gene Transfer into Rat Hepatocytes: Implications for Gene Therapy," The Society of University Surgeons, Resident's Program, Cincinnati, Ohio (February 15, 1992).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p align="center">Substitute for form 1449A/PTO</p> <p align="center">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p align="center">(use as many sheets as necessary)</p>		Complete if Known	
		Application Number	09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002
		Filing Date	November 3, 1998
		First Named Inventor	Joseph P. Vacanti
		Group Art Unit	3738
		Examiner Name	D. Isabella
Sheet 12 of 27	Attorney Docket Number	MIT 6917 (CMCC 450) DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		FONTAINE, et al., "Transplantation of Genetically Altered Hepatocytes Using Cell-Polymer Constructs," <u>Transplantation Proceedings</u> , 25:1002-1004 (February 1993).	
		FRESHNEY, "The Culture Environment: I. Substrate, Gas Phase, and Temperature," <u>Culture of Animal Cells</u> pp55-56 (Alan R. Liss, NY 1983).	
		GASH, "Neural Transplantation: Potential Therapy for Alzheimer's Disease," <u>J. Neural Trans. [Suppl]</u> 24:301-8 (1987).	
		GASH, et al., "Amitotic Neuroblastoma Cells Used for Neural Implants in Monkeys," <u>Science</u> 233(4771):1420-2 (September 26, 1986).	
		GEISS, et al., "Multicenter Survey of Endoscopic Treatment of Vesidoureteral Reflux in Children," <u>Eur. Urol</u> 17:328-329 (1990).	
		GILBERT, et al., "Cell Transplantation of Genetically Altered Cells on Biodegradable Polymer Scaffolds in Syngeneic Rats," <u>Transplantation</u> , 56(2): 423-427 (August, 1993)..	
		GRANDE, et al., "Healing of Experimentally Produced Lesions in Articular Cartilage Following Chondrocyte Transplantation," <u>The Anatomical Record</u> 218:142-148 (1987).	
		GRANDE, et al., "The Repair of Experimentally Produced Defects in Rabbit Articular Cartilage by Autologous Chondrocyte Transplantation," (May 11, 1988).	
		GREEN, "Growth of Cultured Human Epidermal Cells into Multiple Epithelia Suitable for Grafting," <u>Proc. Natl. Acad. Sci. USA</u> 76(11):5665-5668 (November, 1979).	
		GROLLEMAN, et al., "Studies on a Bioerodible Drug Carrier System Based on Polyphosphazene," <u>Journal of Controlled Release</u> 3:143-154 (1986).	

Examiner's Signature	Date Considered
----------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known			
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002	
				Filing Date		November 3, 1998	
				First Named Inventor		Joseph P. Vacanti	
				Group Art Unit		3738	
				Examiner Name		D. Isabella	
Sheet	13	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		GROTH, et al., "Correction of Hyperbilirubinemia in the Glucuronyltransferase-Deficient Rat by Intraportal Hepatocyte Transplantation," <u>Transplant. Proc.</u> 9:313-316 (1977).	
		HAMMOND, et al., "Morphologic Analysis of Tissue-Expander Shape Using a Biomechanical Model," <u>Plastic and Reconstructive Surgery</u> 92(2):255-259 (August, 1993).	
		HARRIS, et al. "Silicone Rubber Substrata: A New Wrinkle in the Study of Cell Locomotion," <u>Science</u> 208:177-179 (1980).	
		HENDREN & ATALA, "Use of Bowel for Vaginal Reconstruction," <u>The Journal of Urology</u> 152:752-755 (August, 1994).	
		HENLY, et al., "Particulate Silicone for Use in Periurethral Injections: A Study of Local Tissue Effects and a Search for Migration," <u>The Journal of Urology</u> 147(4):376A (April, 1992).	
		HENRY, et al., "Nerve Regeneration Through Biodegradable Polyester Tubes," <u>Exp. Neurol.</u> 90(3): 652-676 (December, 1985).	
		INGBER, et al., "Cells as Tensecity Structures: Architectural Regulation of Histodifferentiation by Physical Forces Transduced Over Basement Membrane," <u>Gene Expression During Normal and Malignant Differentiation</u> , L. C. Anderson, et al., editors, pp 13-32 (Academic Press, Orlando, FL 1985).	
		INGBER, et al., "Endothelial Growth Factors and Extracellular Matrix Regulate DNA Synthesis Through Modulation of Cell and Nuclear Expansion," <u>In Vitro Cellular and Developmental Biology</u> 23(5):387-394 (May, 1987).	
		INGBER, "How Does Extracellular Matrix Control Capillary Morphogenesis?" <u>Cell</u> 58:803-805 (September 8, 1989).	
		INGBER, et al., "Control of Capillary Morphogenesis: A Molecular System of Mechanical Switches," <u>J. Cell Biol.</u> , 107:797a (1988).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number Filing Date First Named Inventor Group Art Unit Examiner Name Attorney Docket Number	09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002 November 3, 1998 Joseph P. Vacanti 3738 D. Isabella MIT 6917 (CMCC 450) DIV
Sheet	14	of	27		

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		INGBER, "Growth Control Through Fibronectin-Dependent Modulation of Cell Shape,," <u>J. Cell Biol.</u> 105:219a (1987).	
		INGBER, et al., "Mechanochemical Switching Between Growth Factor-Stimulated Angiogenesis In Vitro: Role of Extracellular Matrix," <u>J. Cell. Biol.</u> , 109:317-330 (1989).	
		JACKSIC, et al., "The Use of 'Artificial Skin' for Burns," <u>Ann. Rev. Med.</u> 38:107-116 (1987).	
		JAUREGYU, et al., "Attachment and Long Term Survival of Adult Rat Hepatocytes in Primary Monolayer Cultures: Comparison of Different Substrata and Tissue Culture Medial Formulations," <u>In Vitro Cellular & Development Biology</u> , 22(1):13-22 (January 1986).	
		JONES, "Degradation of Artificial Tissue Substrates," <u>Cancer Invasion and Metastasis: Biologic and Therapeutic Aspects</u> , 177-185 (Raven Press, NY 1984).	
		JUNQUIERA, et al., <u>1989 Basic Histology</u> , Prentice Hall, pp. 282-283 (1989).	
		KEHNA, et al., "Diffusion of Antibiotics Across Tissue Expanders: An in Vitro Study," <u>Annals of Plastic Surgery</u> 32(4):346-349 (April, 1994).	
		KLGSBURN, "Large-Scale Preparation of Chondrocytes," <u>Methods in Enzymology</u> Vol. LVIII, Academic Press, New York, 1979	
		KLEINMAN, et al., "Use of Extracellular Matrix Components and Cell Culture," <u>Analytical Biochemistry</u> 166:1-13 (1987).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known			
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002	
				Filing Date		November 3, 1998	
				First Named Inventor		Joseph P. Vacanti	
				Group Art Unit		3738	
				Examiner Name		D. Isabella	
Sheet	15	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV	

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		KLOMPMAKER, et al, "Porous Polymer Implants for Repair of Full-Thickness Defects of Articular Cartilage: An Experimental Study in Rabbit and Dog," <u>Biomaterials</u> 13(9):625-634 (1992).	
		KOLATA, "Parkinson Procedure: Fervor Turns to Disillusion," <u>The New York Times</u> , (April 21, 1988).	
		KORDOWER, et al., "An In Vivo and In Vitro Assessment of Differentiated Neuroblastoma Cells as a Source of Donor Tissue for Transplantation," <u>Annals of The New York Academy of Sciences</u> , 495:606-622 (new York 1987).	
		KORDOWER, et al., "Neuroblastoma Cells in Neural Transplants: A Neuroanatomical and Behavioral Analysis," <u>Brain Research</u> , 417:85-98 (1987).	
		KRETSCHMER, et al, "Autotransplantation of Pancreatic Fragments to the Portal Vein and Spleen of Total Pancreatectomized Dogs," <u>Ann. Surg.</u> , 187:79-86 (January, 1978).	
		KUSANO, et al., <u>Acta Japoni Hepato</u> 63:345-351 (1989).	
		LANGER & MOSES, "Biocompatible Controlled Release Polymers for Delivery of Polypeptides and Growth Factors," <u>Journal of Cellular Biochemistry</u> , 45:340-345 (1991).	
		LANGER and VACANTI, "Tissue Engineering," <u>Science</u> 260:920-926 (May 14, 1993).	
		LEONARD, et al., "Endoscopic Injection of Glutaraldehyde Cross-Linked Bovine Dermal Collagen for Correction of Vesidoureteral Reflux," <u>The Journal of Urology</u> 145:115-119 (January, 1991).	
		LEONG, et al., "Bioerodible Polyanhydrides as Drug-Carrier Matrices. I: Characterization, Degradation, and Release Characteristics," <u>Journal of Biomedical Materials Research</u> , 19:941-955 (1985).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known			
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002	
				Filing Date		November 3, 1998	
				First Named Inventor		Joseph P. Vacanti	
				Group Art Unit		3738	
				Examiner Name		D. Isabella	
Sheet	16	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		LETOURNEAU, "Possible Roles of Cell-to-Substratum Adhesion in Neuronal Morphogenesis," <u>Developmental Biology</u> , 44:77-91 (1975)	
		LEWIN, "Cloud Over Parkinson's Therapy," <u>Science News</u> , 240: 390-392 (1988).	
		LEWIN, "Disappointing Brain Graft Results," <u>Science</u> , p. 1407 (June 10, 1988).	
		LI, et al., "Influence of a Reconstituted Basement Membrane and its Components of Casein Gene Expression and Secretion in Mouse Mammary Epithelial Cells," <u>Proc. Natl. Acad. Sci. USA</u> , 84:136-140 (1987).	
		LUCAS, et al, "Ectopic Induction of Cartilage and Bone by Water-Soluble Proteins from Bovine Bone Using a Ppolyanhydride Delivery Vehicle," <u>Journal of Biomedical Materials Research</u> 24(7):901-911 (1990).	
		MACKLIS, et al., "Cross-Linked Collagen Surface for Cell Culture that is Stable, Uniform, and Optically Superior to Conventional Surfaces," <u>In Vitro Cellular & Developmental Biology</u> , 21(3)(1): 189-194 (March 1985).	
		MADISON, et al., "Increased Rate of Peripheral Nerve Regeneration Using Bioresorbable Nerve Guides and Laminin-Containing Gel," <u>Exp. Neurol.</u> , 88(3) 767-772 (June 1985).	
		MADISON, et al., "Nontoxic Nerve Guide Tubes Support Neovascular Growth in Transected Rat Optic Nerve," <u>Exp. Neurol.</u> , 86:448-461 (1984).	
		MADISON, et al., "Peripheral Nerve Regeneration with Entubulation Repair: Comparison of Biodegradable Nerve Guides Versus Polyethylene Tubes and the Effects of a Laminin-Containing Gel," <u>Exp. Neurol.</u> , 95(2)387-390 (February, 1987).	
		MALIZIA, et al., "Migration and Granulomatous Reaction After Periurethral Injection of Polytef (Teflon)," <u>JAMA</u> , 251(24):3277-3281 (June, 1984).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>				Complete If Known	
				<p>Application Number</p> <p>09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002</p>	
				<p>Filing Date</p> <p>November 3, 1998</p>	
				<p>First Named Inventor</p> <p>Joseph P. Vacanti</p>	
				<p>Group Art Unit</p> <p>3738</p>	
				<p>Examiner Name</p> <p>D. Isabella</p>	
Sheet	17	of	27	<p>Attorney Docket Number</p> <p>MIT 6917 (CMCC 450) DIV</p>	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		MARCIANO and GASH, "Structural and Functional Relationships of Grafted Vasopressin Neurons," <u>Brain Res.</u> , 370(2):338-342 (April 9, 1986).	
		MATAS, et al., "Hepatocellular Transplantation for Metabolic Deficiencies: Decrease of Plasma Bilirubin in Gunn Rats," <u>Science</u> 192:892-894 (1976).	
		MATOUSCHEK, "Die Behandlung des vesikorenenalen Refluxes durth Transurethrale Einspritzung von Teflonpaste," <u>Urologe A</u> 20:263-264 (1981).	
		MESNIL, et al., "Cell Contact but Not Junctional Communication (Dye Coupling) with Biliary Epithelial Cells is Required for Hepatocytes to Maintain Differentiated Functions," <u>Exper. Cell. Res.</u> 173:524-533 (1987).	
		MICHAPOULOS & PITOT, "Primary Culture of Parenchymal Liver Cells on Collagen Membranes," <u>Exper. Cell. Res.</u> 94:70-78 (1975).	
		MILLARUELO, "Role of Plasminogen Activator and its Inhibitors in Axonal Outgrowth and Regeneration In Vivo," <u>Caltech Biology</u> , (1987).	
		MINATO, et al., "Transplantation of Hepatocytes for Treatment of Surgically Induced Acute Hepatic Failure in the Rat," <u>Eur. Surg. Res.</u> , 16:162-169 (1984).	
		MITO, et al., "Hepatocellular Transplantation," <u>Department of Surgery, Asahikawa Medical College</u> 078 4-5 Nishi-Kagura, Asahikawa, Japan	
		MITTLEMAN & MARRACCINI, "Pulmonary Teflon Granulomas Following Periurethral Teflon Injection for Urinary Incontinence," <u>Arch. Pathol. Lab. Med.</u> 107:611-612 (November 1983).	
		MOONEY, "Control of Hepatocyte Function Through Polymer-Substrate Modulation," <u>Thesis Proposal - Department of Chemical Engineering, Massachusetts Institute of Technology</u> (September 22, 1989).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTQSB08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p>Substitute for form 1449/APTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>				Complete If Known			
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002	
				Filing Date		November 3, 1998	
				First Named Inventor		Joseph P. Vacanti	
				Group Art Unit		3738	
				Examiner Name		D. Isabella	
Sheet	18	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		MOONEY, "Switching from Differentiation to Growth in Hepatocytes: Control by Extracellular Matrix," <u>J. Cell. Phys.</u> (151):497-505 (1992).	
		MOONEY, et al., "Induction of Hepatocyte Differentiation by the Extracellular Matrix and an RGD-Containing Synthetic Peptide," <u>Mat. Res. Soc. Symp. Proc.</u> 252 (1992).	
		MOONEY, et al., "Integrating Cell Transplantation and Controlled Drug Delivery Technologies to Engineer Liver Tissue," (abstract) Materials Research Society, (April 17-21, 1995).	
		MOONEY, et al., "Tissue Engineering Using Cells and Synthetic Polymers," <u>Transplantation Reviews</u> , 7(3):153-162 (1993).	
		MOUNZER, et al., "Polyglycolic Acid Mesh in Repair of Renal Injury," <u>Urology</u> 28(2):172-130 (1986).	
		MOVITZ, "Accessory Spleens and Experimental Splenosis Principles of Growth," <u>The Chicago Medical School Quarterly</u> , 26(4):183-187 (Winter-Spring 1967).	
		NAHI, et al., "Successful Islet Transplantation in Spontaneous Diabetes," <u>Surgery</u> 86:218-226 (1979)	
		NASTELIN, "Pancreatic Islet Cell Transplantation: Optimization of Islet Cell Adhesion by Altering Polymer Surface Characteristics," Harvard-M.I.T. Division of Health Sciences and Technology (February 1990).	
		NAUGHTON, et al., "Long-Term Growth of Rat Bone Marrow Cells in a Three-Dimensional Matrix," Medical Laboratory Sciences Department, Hunter College School of Health Sciences, New York, <u>The Anatomical Record</u> , 218(1):97a (May, 1987).	
		NAUGHTON, et al., Granulopoiesis and Colony Stimulating Factor Production in Regenerating Liver," <u>Exp. Hematol.</u> , 10(5):451-458 (May, 1982).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTOSB08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449/APTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known			
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002	
				Filing Date		November 3, 1998	
				First Named Inventor		Joseph P. Vacanti	
				Group Art Unit		3738	
				Examiner Name		D. Isabella	
Sheet	19	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		NAUGHTON, et al., "Erythropoietin Production by Macrophages in the Regenerating Liver," <u>Journal of Surgical Oncology</u> 30:184-197 (1985).	
		NOTTER, et al, "Neuronal Properties of Monkey Adrenal Medulla in vitro," <u>Cell Tissue Res.</u> , 244(1):69-76 (1986).	
		NYILAS, et al, "Peripheral Nerve Repair with Bioresorbable Prosthesis," <u>Trans. Am. Soc. Artif. Intern. Organs</u> , 29:307-313 (1983).	
		O'CONNOR, et al., "Grafting of Burns with Cultured Epithelium Prepared from Autologous Epidermal Cells," <u>The Lancet</u> , I(8210):75-78 (January, 1981).	
		O'DONELL & PURI, "Treatment of Vesicoureteric Reflux by Endoscopic Injection of Teflon," <u>British Medical Journal</u> 289:7-9 (July 7, 1984).	
		O'C. HAMILTON, "Miracle Cures May be in Your Cells," <u>BusinessWeek</u> (December 6, 1993).	
		OELLRICH, R. G., et al. "Biliary Atresia," <u>Neonatal Network</u> pp 25-30 (April, 1987).	
		OLIWENSTEIN, "The Power of Plastics," <u>Discover</u> p. 18 (December, 1989).	
		OMERY, "A Nursing Perspective of the Ethical Issues Surrounding Liver Transplantation," <u>Heart & Lung</u> 17(6):626-630 (November, 1988).	
		PAIGE, et al., "De Novo Cartilage Generation Using Calcium Alginate-Chondrocyte Constructs," Children's Hospital, Boston, MA, Plastic Surgery Research Council Meeting; N.E. Society of Plastic and Reconstructive Surgeons Meeting; and North Eastern Society of Plastic Surgeons Meeting pp 1-34 (1993).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTOSB08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>		Complete If Known			
		Application Number	09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002		
		Filing Date	November 3, 1998		
		First Named Inventor	Joseph P. Vacanti		
		Group Art Unit	3738		
		Examiner Name	D. Isabella		
Sheet	20	of	27	Attorney Docket Number	MIT 6917 (CMCC 450) DIV

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		PASIK, <u>Annals of the N.Y. Academy of Science</u> , 495:674-675 (1987).	
		PATTERSON, et al., "Adrenal Chromaffin Cell-Derived Cholinergic Neurons for Brain Transplants," <u>Caltech Biology</u> pp 201-202 (1987).	
		PERLOW, M. J., "Brain Grafting as a Treatment for Parkinson's Disease," <u>Neurosurgery</u> 20(2):335-342 (1987).	
		PIMPL, et al., "Experimentelle Studie zur Frage der Transplantatkonditionierung und Transplantatgroße bei heterotoper autologer Milztransplantation," <u>Lagenbecks Archiv</u> 37215-36218 (Salzburg 1984).	
		PIMPL, et al., "Perfusion of Autologous Splenic Grafts in Correlation with Specific Immunological Functions An Experimental Study in Pigs," <u>Eur. Surg. Res.</u> 19:53-61 (1987).	
		PITMAN, et al., "The Use of Adhesives in Chondrocyte Transplantation Surgery: In-Vivo Studies," <u>Bulletin of the Hospital for Joint Diseases Orthopaedic Institute</u> 49(2):213-220 (1989).	
		PTASINSKA-URBANSKA, et al, "Intrascleral Introduction of Isolated Allogeneic Chondrocytes Capable of Cartilage Reformation in Rabbits; Possible Procedure in Treatment of Detachment of the Retina," <u>Exp. Eve. Res.</u> , 24(3):241-247 (1977).	
		PUELACHER, W. C., et al., "Tissue-Engineered Growth of Cartilage: the Effect of Varying the Concentration of Chondrocytes Seeded onto Synthetic Polymer Matrices," <u>Int. J. Oral Maxillofac. Surg.</u> , 23:49-53 (1994).	
		RAMES & AARTONSON, "Migration of Polytef Paste to the Lung and Brain Following Intravesical Injection for the Correction of Reflux," <u>Pediatric Surgery</u> 6(1):239-240 (January, 1991).	
		REDMOND, et al., "Fetal Neuronal Grafts in Monkeys Given Methyphenyltetrahydropyridine," <u>The Lancet</u> , pp 1125-1127 (May 17, 1986).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p align="center">Substitute for form 1449A/PTO</p> <p align="center">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p align="center">(use as many sheets as necessary)</p>				Complete If Known		
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002
				Filing Date		November 3, 1998
				First Named Inventor		Joseph P. Vacanti
				Group Art Unit		3738
				Examiner Name		D. Isabella
Sheet	21	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		REDMOND, et al., "Transplants of Primate Neurons," <u>The Lancet</u> , 2(8510):1046 (November 1, 1986).	
		REID, et al. "Long-Term Cultures of Normal Rat Hepatocytes on Liver Biomatrix," <u>Ann. NY Acad. Sci.</u> 349:70-76 (1980)	
		RETIK, et al., "Management of Severe Hypospadias with a 2-Stage Repair," <u>Microbiology & Immunology</u> 152:749-751 (August, 1984).	
		RHINE, et al., "Polymers for Sustained Macromolecule Release: Procedures to Fabricate Reproducible Delivery Systems and Control Release Kinetics," <u>Journal of Pharmaceutical Sciences</u> , 69(3):265-269 (March, 1980).	
		ROSEN, "Bioerodible Polyanhydrides for Controlled Drug Delivery," 1983 Butterworth & Co. (Publishers) Ltd.	
		ROSEN, "Bioerodible Polymers for Controlled Release Systems," <u>Controlled Release Systems: Fabrication Technology</u> , II:83-110	
		SAPOZHNIKOVA, et al., "Morphological Changes in Splenic Autografts Following Splenectomy: Experimental and Clinical Findings," <u>Biological Abstracts</u> , 86(76896) (1987).	
		SASAKI, "Neovascularization in the Splenic Autograft Transplanted into Rat Omentum as Studied by Scanning Electron Microscopy of Vascular Casts," <u>Virchows Arch.</u> , 409:325-334 (1986).	
		SAWADA, et al., "Effects of Extracellular Matrix Components on the Growth and Differentiation of Cultured Rat Hepatocytes," <u>In Vitro Cellular & Development Biology</u> , 23(4): 267-273 (April, 1987).	
		SCHMECK, "Doctors try to Capitalize on the Liver's Ability to Regenerate Itself," <u>The New York Times Medical Science</u> , (May 16, 1989).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete If Known			
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002	
				Filing Date		November 3, 1998	
				First Named Inventor		Joseph P. Vacanti	
				Group Art Unit		3738	
				Examiner Name		D. Isabella	
Sheet	22	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		SCHUBERT & BAIRD, "Multiple Influences of a Heparin-Binding Growth Factor for Neuronal Development," <u>The Journal of Cell Biology</u> , 104:635-643 (March 1987).	
		SECKLE, "Nerve Regeneration Through Synthetic Biodegradable Nerve Guides: Regulation by the Target Organ," <u>Plast. Reconstr. Surg.</u> , 74(2):173-81 (August, 1974).	
		SELDEN, et al., "The Pulmonary Vascular Bed as a Site for Implantation of Isolated Liver Cells in Inbred Rats," <u>Transplantation</u> , 38(1):81-83 (July, 1984).	
		SHINE, et al., "Cultured Peripheral Nervous System Cells Support Peripheral Nerve Regeneration Through Tubes in the Absence of Distal Nerve Stump," <u>Journal of Neuroscience Research</u> , 14:393-401 (1985).	
		SIEGEL & LANGER, "Controlled Release of Polypeptides and Other Macromolecules," <u>Pharmaceutical Research</u> , pp 2-10 (1984).	
		SIRICA, A., et al, "Use of Primary Cultures of Adult Rat Hepatocytes on Collagen Gel-Nylon Mesh to Evaluate Carcinogen-Induced Unscheduled DNA Synthesis," <u>Cancer Research</u> , 40:3259-3267 (September 1980).	
		SIRICA, et al., "Fetal Phenotypic Expression by Adult Rat Hepatocytes on Collagen Gel/Nylon Meshes," <u>Proc. Natl. Acad. Sci. USA</u> , 76(1):283-287 (January, 1979).	
		SLADEK & SHOULSON, "Neural Transplantation: A Call for Patience Rather Than Patients," <u>Science</u> , 240:386-388 (June 10, 1988).	
		SLADEK, "Transplantation of Fetal Dopamine Neurons in Primate Brain Reverses MPTP Induced Parkinsonism," <u>Progress in Brain Research</u> , 71:309-323 (1987).	
		SLADEK, et al, "Reversal of Parkinsonism by Fetal Nerve Cell Transplants in Primate Brain," <u>Annals of the New York Academy of Sciences</u> , 495:641-657 (1987).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete If Known	
				Application Number Filing Date First Named Inventor Group Art Unit Examiner Name Attorney Docket Number	09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002 November 3, 1998 Joseph P. Vacanti 3738 D. Isabella MIT 6917 (CMCC 450) DIV
Sheet	23	of	27		

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		SLADEK, et al., "Survival and Growth of Fetal Catecholamine Neurons Transplanted Into Primate Brain," <u>Brain Research Bulletin</u> , 17:809-818 (1986).	
		SOMMER, et al., "Hepatocellular Transplantation for Treatment of D-Galactosamine-Induced Acute Liver Failure in Rats," <u>Transplant. Proc.</u> , 11(1):578-584 (March, 1979).	
		STEIN, "Three Dimensional Tissue Reorganization in Hepatocyte Transplantation," American College of Surgeons, Surgical Forum, (October, 1991).	
		STEMPLE, <u>Altech Biology</u> (1987).	
		STROM, et al., "Isolation, Culture, and Transplantation of Human Hepatocytes," <u>JNCL</u> , 68(5):771-778 (May 1982).	
		SUDHAKARAN, et al., "Modulation of Protein Synthesis and Secretion by Substratum in Primary Cultures of Rat Hepatocytes," <u>Exper. Cell Res.</u> 167:505-516 (1986).	
		SULLIVAN, "Spinal Injury Research Yields a Glimmer of Hope," <u>The New York Times</u> p.C6 (July 14, 1987).	
		SUTHERLAND, D. E., et al., "Hepatocellular Transplantation in Acute Liver Failure," <u>Surgery</u> 82(1):124-132 (July 1977).	
		TACHIBANA, "Ureteral Replacement Using Collagen Sponge Tube Grafts," <u>The Journal of Urology</u> 133(4):866-869 (April, 1985).	
		TAKEDA, et al., "Hepatocyte Transplantation in Biodegradable Polymer Scaffolds Using the Dalmatian Dog Model of Hyperuricosuria," <u>Transplantation Proceedings</u> 27(1):635-636 (February, 1995).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-95)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>				Complete If Known			
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002	
				Filing Date		November 3, 1998	
				First Named Inventor		Joseph P. Vacanti	
				Group Art Unit		3738	
				Examiner Name		D. Isabella	
Sheet	24	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		TAVASSOLI, et al., "Studies on Regeneration of Heterotopic Splenic Autotransplants," <u>Blood</u> , 41(5):701-709 (May, 1973).	
		THOMPSON, "Implantable Bioreactors: Modern Concepts of Gene Therapy," <u>Current Communications in Molecular Biology</u> , Daniel Marshak, et al., editors, pp 143-147 (Cold Spring Harbor Laboratory, 1989).	
		THOMPSON, J. A., "Heparin-Binding Growth Factor 1 Induces the Formation of Organoid Neovascular Structures in Vivo," <u>Proc. Natl. Acad. Sci USA</u> , 86:7928-27932 (October, 1989).	
		THUROFF, et al., "Cultured Rabbit Vesical Smooth Muscle Cells for Lining of Dissolvable Synthetic Prosthesis," <u>Urology</u> , 21(2):155-158 (1983).	
		TOMOMURA, et al., "The Control of DNA Synthesis in Primary Cultures of Hepatocytes From Adult and Young Rats: Interactions of Extracellular Matrix Components, Epidermal Growth Factor, and the Cell Cycle," ©1987 Alan R. Liss, Inc.	
		Unipoint Industries, Inc., "Polyvinyl Alcohol Foam for Surgical And Industrial Use," Product Review	
		UNOS Update, "National Cooperative Transplantation Study Completed," 7(10) (October/November 1991).	
		UPTON, et al., "Neocartilage Derived from Transplanted Perichondrium: What is it? <u>Plastic and Reconstructive Surgery</u> 68(2): 166-174 (1981).	
		UYAMA, et al., "Delivery of Whole Liver-Equivalent Hepatocyte Mass Using Polymer Devices and Hepatotrophic Stimulation," <u>Transplantation</u> 55:932-935 (April, 1993).	
		VACANTI, et al., "Formation of New Cartilage in Vivo by Implantation of Cell-Polymer Constructs Created in Vitro,"	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>				Complete If Known	
				Application Number	09/185,360
				Filing Date	November 3, 1998
				First Named Inventor	Joseph P. Vacanti
				Group Art Unit	3738
				Examiner Name	
Sheet	25	of	27	Attorney Docket Number	MIT 6917 (CMCC 450) DIV

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		VACANTI, et al., "Synthetic Polymers Seeded with Chondrocytes Provide a Template for New Cartilage Formation," <u>Journal of the American Society of Plastic and Reconstructive Surgeons, Inc.</u> , 88(5):753-759 (November 1991).	
		VACANTI, "Tissue Engineered Composites of Bone and Cartilage Using Synthetic Polymers Seeded with Two Cell Types," <u>39th Annual Meeting of the Orthopaedic Research Society</u> (February 15-18, 1993).	
		VACANTI, "Beyond Transplantation," <u>Arch. Surgery</u> 123:545-549 (May 1988).	
		VACANTI, et al., "Engineered Bone from Polyglycolic Acid Polymer Scaffold and Periosteum," (abstract) <u>Materials Research Society</u> , (April 17-21, 1985).	
		VACANTI, J.P., et al., "Selective Cell Transplantation Using Bioabsorbable Artificial Polymers as Matrices," <u>Journal of Pediatric Surgery</u> , 23(1):3-9 (January 1988).	
		VAN DER KWAST, et al., "Establishment and Characterization of Long-Term Primary Mouse Urothelial Cell Cultures," <u>Urological Research</u> , 17(1):290-293 (1989).	
		VARGO, "Infection as a Complication of Liver Transplant," <u>Critical Care Nurse</u> 9(4):52-62	
		VIJG, et al., "UV-Induced DNA Excision Repair in Rat Fibroblasts During Immortalization and Terminal Differentiation in Vitro," <u>Exp. Cell. Res.</u> 167:517-530 (1986).	
		VORSTMAN, et al., "Polytetrafluoroethylene Injection for Urinary Incontinence in Children," <u>The Journal of Urology</u> 133(2):248-250 (February, 1985).	
		VROEMEN, et al., "Hepatocyte Transplantation for Enzyme Deficiency Disease in Congenic Rats," <u>Transplantation</u> , 42(2):130-135 (1986).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known			
				Application Number		09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002	
				Filing Date		November 3, 1998	
				First Named Inventor		Joseph P. Vacanti	
				Group Art Unit		3738	
				Examiner Name		D. Isabella	
Sheet	26	of	27	Attorney Docket Number		MIT 6917 (CMCC 450) DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		WALKER, et al., "Injectable Bioglass as a Potential Substitute for Injectable Polytetrafluoroethylene," <u>The Journal of Urology</u> 148(1):645-647	
		WALTON, et al., "Tissue Engineering of Biomaterials for Composite Reconstruction: An Experimental Model," <u>Annals of Plastic Surgery</u> 30(2):104-110 (February, 1993).	
		WHITAKER, "Scientists Growing Tissue From 'Seed'," <u>The Boston Globe</u> (Monday, February 22, 1993).	
		WOZNEY, et al., "Novel Regulators of Bone Formation: Molecular Clones and Activities," <u>Science</u> , 242:1528-1534 (December 16, 1988).	
		YANNAS, et al., "Design of an Artificial Skin. I. Basic Design Principles," <u>Journal of Biomedical Materials Research</u> 14:65-81 (1980).	
		YANNAS, et al., "Regeneration of Sciatic Nerve Across 15 mm Gap by Use of a Polymeric Template," <u>Polym. Sci. Technol. Iss. Adv. Biomed. Polymer</u> 35:109 (1987).	
		YANNAS, "Wound Tissue Can Utilize a Polymeric Template to Synthesize a Functional Extension of Skin," <u>Science</u> 215:174-176 (1982).	
		YANNAS, et al, "Artificial Skin: A Fifth Route to Organ Repair and Replacement," <u>Iss. Polym. Biomaterial</u> , 106:221-230 (1986).	
		YANNAS, et al., "Polymeric Template Facilitates Regeneration of Sciatic Nerve Across 15 MM Gap," <u>Polymer. Material Sci. Eng.</u> 53:216-218 (1985).	
		YANNAS, et al., "Suppression of in Vivo Degradability and of Immunogenicity of Collagen by Reaction with Glycosaminoglycans," <u>Polymer. Prepar. Am. Chem. Soc. Div. Polym. Chem.</u> , 16(2): 209-214 (1975).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete If Known	
				Application Number	
				09/185,360 U.S. Patent No. 6,348,069 Issued February 19, 2002	
				Filing Date	
				November 3, 1998	
				First Named Inventor	
Joseph P. Vacanti					
Group Art Unit					
3738					
Examiner Name					
D. Isabella					
Attorney Docket Number					
MIT 6917 (CMCC 450) DIV					
Sheet	27	of	27		

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		YANNAS, "What Criteria Should be Used for Designing Artificial Skin Replacement and How Well do the Current Grafting Materials Meet These Criteria?" <u>J. of Trauma</u> , 24(9):S29-S39 (1984).	
		Report of the International Reflux Study Committee, "Medical Versus Surgical Treatment of Primary Vesicoureteral Reflux: A Prospective International Reflux Study in Children," <u>The Journal of Urology</u> 125:277-283 (March, 1981).	
		ZUND, et al., "A New Approach for a Bioprothetic-Heart Valve," <u>The European Association for Cardio-Thoracic Surgery</u> , (January 31, 1995).	

Examiner's Signature		Date Considered	
-------------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.